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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/834,926 04/16/01 POCHLAUER

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EXAMINER

ZUCKER, P

ART UNIT

PAPER NUMBER

1623

DATE MAILED:

08/10/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/834,926

Applicant(s)

POCHLAUER ET AL.

Examiner

Paul A. Zucker

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1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) 1-10 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. Claims 1-10 are objected to because of the following informalities: There are extra spaces in line 1 after the claim numbers. These spaces should be removed.
Appropriate correction is required.
2. Claim 7 is objected to because of the following informalities: There are extra spaces between words in line 3 because of forced justification. These spaces should be removed. Appropriate correction is required.
3. Claim 8 is objected to because of the following informalities: There are extra spaces between the solvent names in line 2 because of forced justification. These spaces should be removed. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1,2 and 6 recite the phrase "enzyme-catalyzed addition of a cyanide group donor"(lines 6,4-5,and 5-6, respectively). This phrase leaves in doubt that which Applicant intends to be added to the aldehyde or ketone. In other words, it is not clear from this phrase that the elements of hydrogen cyanide are being added. This phrase therefore renders the

claim indefinite. The rejection of dependant claims which fail to obviate the deficiencies of independent claims render said dependant claims indefinite for reasons of record.

5. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 5 recites the phrases "a few minutes" or "up to a number of hours" (line 5). These phrases leave the time span contemplated poorly defined and therefore render the claim indefinite.
6. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 9 recites the phrases "readily separable by distillation" (line 4). The word "readily" is undefined and therefore renders the claim indefinite.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1–4 are rejected under 35 U.S.C. 102(b) as being anticipated by Hashimoto et al (US 5,580,765 12-1996). Hashimoto discloses the synthesis of optically pure

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mandelic acid derivatives (Example 5, Column 6, line 37- Column 7, line 15) via the enzyme catalyzed addition of hydrogen cyanide followed by acidic hydrolysis and recrystallization from benzene (Column 4, lines 49-51). Hashimoto also discloses other aromatic substrates (Column 3, lines 42-57). Hashimoto's disclosure therefore anticipates the above-enumerated claims.

8. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Hashimoto et al (US 5,580,765 12-1996). Hashimoto discloses (Table 2, Column 6, lines 55-66, 1st, 2nd and 3rd entries) optically and chemically pure 2-, 3-, and 4-chloromandelic acids having 100 % ee. A compound is defined by its atoms and bonds and is not distinguished by the manner by which it is made. Hashimoto's disclosure therefore anticipates Claim 10.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hashimoto et al (US 5,580,765 12-1996) and further in view of Yu et al (US 4,105,783 08-1978). Hashimoto teaches the synthesis of optically pure mandelic acid derivatives (Example 5, Column 6, line 37- Column 7, line 15) via the enzyme-

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catalyzed addition of hydrogen cyanide followed by acidic hydrolysis and their purification by recrystallization from benzene. Hashimoto states (Column 4, lines 47-51) "Then, the supernatant may be extracted with an organic solvent in an acidic condition, followed by repeated recrystallization from benzene, etc., to obtain a high purity crystal. Hashimoto is silent with respect to the temperature of the nitrile hydrolysis reaction (instant claim 6) however a temperature sufficient to effect hydrolysis is clearly implicitly taught. Since Hashimoto teaches hydrolysis of the nitrile in an organic solvent it would be obvious for one of ordinary skill in the art to realize that the recrystallization could be carried out in the hydrolysis medium. Similarly, since the use of binary solvent mixtures for recrystallizations is common laboratory practice, one of ordinary skill in the art would realize that difficulties encountered in extracting the α -hydroxycarboxylic acid into the aromatic recrystallization solvent could be overcome by use of a co-solvent in which the α -hydroxycarboxylic was more soluble. While Hashimoto only explicitly sets forth benzene as a recrystallization solvent the word "etc." following the word "benzene" must be read as "and the like" and clearly contemplates the instant claimed solvents: toluene, xylene, ethylbenzene, etc. all of which are hydrophobic aromatic solvents. Clearly the use of simple substituted benzenes as solvents cannot impart patentability over a known process using benzene. The Examiner also notes that the limitation of a process with respect to ranges of time and temperature does not impart patentability to a process when such values are those which would be determined by one of ordinary skill in the art in achieving optimum operation of the

process. Clearly time, temperature and solvent compositions are all result-effective variables that one of ordinary skill in the art seeks to optimize when attempting to purify a compound via a crystallization experiment. Thus it would have been obvious for one of ordinary skill in the art to have performed this invention at the time of its creation. The motivation is to produce mandelic acid which is a commercially valuable compound which Yu teaches can be used to treat skin conditions (Column 3, lines 24-33).

Conclusion

10. Claims 1-10 are outstanding. Claims 1-10 are rejected.

11. The prior art made of record and not relied upon for rejections in this action are considered pertinent to applicant's disclosure.

Endo et al US Patent 5,223,416 06-1993

Discloses the preparation of mandelic acid and derivatives from benzaldehydes and hydrocyanic acid.

Hashimoto et al US Patent 5,714,357 02-1998

Discloses the preparation of non-racemic mandelic acid and derivatives.

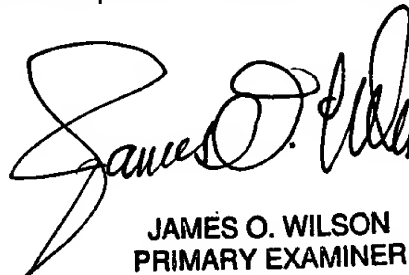
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul A. Zucker whose telephone number is 703-306-0512. The examiner can normally be reached on Monday-Friday 7:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Geist can be reached on 703-308-1701. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

PAZ
August 9, 2001



JAMES O. WILSON
PRIMARY EXAMINER
GROUP 1600